MQSA Facility Certification Requirements for Full Field Digital Mammography (FFDM) Systems using Computed Radiography (CR) detectors

Approved FFDM-CR Systems without an Accreditation Body:

Fuji Computed Radiography

Requirements

1. Facility Status Information

a. Facility Name and FDA Facility ID Number
b. FDA Certificate Expiration Date
c. Current Accreditation Body for Screen-Film or Full Field Digital Mammography (FFDM) Unit(s)
d. Accreditation Expiration Date
e. Facility Contact Person for FFDM-CR
f. Contact Person's Title
g. Contact Person's Telephone, Fax, E-mail
h. Facility Address
i. Facility Owner

2. X-ray Unit Identification

a. Machine Manufacturer
b. Machine Model
c. Year of Manufacture
d. Serial Number

3. FFDM-CR Image Reader Identification

a. Image Reader Manufacturer
b. Image Reader Model
c. Year of Manufacture
d. Serial Number (if applicable)

4. FFDM-CR Acquisition Workstation or Console Identification

a. Acquisition Workstation or Console Manufacturer
b. Acquisition Workstation or Console Model
c. Year of Manufacture
d. Serial Number (if applicable)

5. Identification of Printer for Hard Copy Interpretation (mandatory even for facilities performing only soft copy interpretation)

a. Printer Manufacturer
b. Printer Model
c. Year of Manufacture
d. Serial Number

6. Final Interpretation Review Monitor Identification (if soft copy display is available)

a. Monitor Manufacturer

b. Monitor Model
c. Year of Manufacture
d. Serial Number

7. Phantom Identification

a. Phantom Manufacturer
b. Phantom Model

8. Personnel Qualifications

a. Interpreting Physicians who are qualified to interpret full field digital mammograms (see Qualified Personnel)
b. Radiological Technologists who are qualified to perform full field digital mammography examinations and the manufacturer recommended quality assurance tests (see Qualified Personnel)
c. Medical Physicists who are qualified to perform mammography equipment evaluations (MEE) and/or surveys of full field digital mammography units (see Qualified Personnel)

9. Report of Mammography Equipment Evaluation (MEE) (must have been conducted in accordance with 900.12(e)(10) within the 6 months prior to the request for use approval)

a. Statement that equipment performance, as required under the following sections of the MQSA final regulation 21 CFR 900.12(b), is met:
   (1) Prohibited Equipment
   (2) Specifically Designed for Mammography
   (3) Motion of Tube-Image Receptor Assembly
   (4)(iii) Removable Grid (if applicable to the mammography system used)
   (5) Beam Limitation and Light Fields
   (6) Magnification
   (7) Focal Spot Selection
   (8) Compression
   (9) Technique Factor Selection and Display
   (10) Automatic Exposure Control
   (14) Lighting (if hard copy display is used for image evaluation)
   (15) Film Masking Devices (if hard copy display is used for image evaluation)
b. The results of the following quality control tests as required under the following sections of the MQSA final regulations 21CFR 900.12(e):
   (4)(iii) Compression Device Performance (May submit test results from a previous annual survey if done within the 6 months prior to request for approval)
   (5)(i) Automatic Exposure Control Performance (if applicable to the FFDM-CR system used)
   (5)(ii) Kilovoltage Peak Accuracy and Reproducibility (May submit test results from a previous annual survey if done within the 6 months prior to request for approval)
   (5)(iii) Focal Spot Condition (Resolution Test)
   (5)(iv) Beam Quality and Half-Value Layer

(5)(v) Breast Entrance Air Kerma and AEC Reproducibility (if applicable to the FFDM-CR system used)
(5)(vi) Dosimetry
(5)(vii) X-Ray Field/Light field/Image receptor/Compression paddle alignment
(5)(ix) System Artifacts
(5)(x) Radiation Output (May submit test results from a previous annual survey if done within the 6 months prior to request for approval)
(5)(xi) Decompression (or alternative standards allowed for these requirements) (May submit test results from a previous annual survey if done within the 6 months prior to request for approval)
(6) Quality Control Tests – Other Modalities (Facilities must perform all applicable FFDM-CR manufacturer recommended quality control tests including the medical physicist's tests for the Soft Copy Display system)

c. The results of the phantom image quality tests, including a sample image
d. If any of the requirements in 9 a, b, or c are not met, submit documentation of successful corrective action
e. If any of the requirements in 9 a or b are not performed, explain why the requirement is not applicable
f. Date of the MEE
g. Name and address of the physicist(s) who performed the MEE

Note: Because no component of an annual survey may be older than 14 months, if the facility submits test results from a previous annual survey, it will have to ensure that future surveys are timed so that all components of the survey are completed within the 14 month timeframe.

10. FFDM-CR Manufacturer's Quality Control Program

a. Name of the Quality Control Manual
b. Year published
c. Revision number, if not the original
d. Printing number, if not the original

11. Signature

Qualified Personnel

Interpreting Physicians

PERSONNEL QUALIFICATIONS: INTERPRETING PHYSICIANS WHO ARE QUALIFIED TO INTERPRET DIGITAL MAMMOGRAMS
List the current interpreting physicians who:

(1) meet all the requirements of CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *; AND
(2) began interpreting full field digital mammograms prior to April 28, 1999.

List the current interpreting physicians who:

(1) meet all the requirements of 21 CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;
(2) began interpreting full field digital mammograms after April 28, 1999; AND
(3) have 8 hours of initial training in Full Field Digital Mammography*.

* Supporting documentation for these requirements will be checked during annual MQSA inspections.

Radiologic Technologists

PERSONNEL QUALIFICATIONS: RADIOLOGIC TECHNOLOGISTS WHO ARE QUALIFIED TO PERFORM DIGITAL MAMMOGRAMS
List the current radiologic technologists who:

(1) meet all the requirements of 21 CFR 900.12(a)(2) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *; AND
(2) began performing full field digital mammography examinations prior to April 28, 1999.

List the current radiologic technologists who:

(1) meet all the requirements of 21 CFR 900.12(a)(2) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;
(2) began performing full field digital mammography examinations after April 28, 1999; AND
(3) have 8 hours of initial training in Full Field Digital Mammography*.

*Supporting documentation for these requirements will be checked during annual MQSA inspections.

Medical Physicists

PERSONNEL QUALIFICATIONS: MEDICAL PHYSICISTS WHO ARE QUALIFIED TO PERFORM FFDM SURVEYS
List the current medical physicists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *; AND
(2) began performing equipment evaluations and/or surveys of full field digital mammography units prior to April 28, 1999

List the current medical physicists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;
(2) began performing equipment evaluations and/or surveys of full field digital mammography units after April 28, 1999; AND
(3) have 8 hours of initial training in Full Field Digital Mammography*.

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* Supporting documentation for these requirements will be checked during annual MQSA inspections.

Lead Interpreting Physician Attestation to Staff Personnel Qualifications

To the best of my knowledge and my belief, the information provided in this document is true and correct. I understand that FDA may request additional information to substantiate the statements made in the document. I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.

Signature (Lead Interpreting Physician) _____
Print Name_____
Date_____

MQSA Facility Certification Requirements for Full Field Digital Mammography (FFDM) Systems using Direct Radiography (DR) detectors

Approved FFDM-DR Systems without an Accreditation Body:

None

Requirements

1. Facility Status Information

a. Facility Name and FDA Facility ID Number
b. FDA Certificate Expiration Date
c. Current Accreditation Body for Screen-Film or Full Field Digital Mammography (FFDM) Unit(s)
d. Accreditation Expiration Date
e. Facility Contact Person for FFDM-DR
f. Contact Person's Title
g. Contact Person's Telephone, Fax, E-mail
h. Facility Address
i. Facility Owner

2. FFDM-DR Unit Identification

a. Machine Manufacturer
b. Machine Model
c. Year of Manufacture
d. Serial Number

3. FFDM-DR Digital Image Receptor Identification (if interchangeable)

a. Receptor Manufacturer
b. Receptor Model
c. Year of Manufacture
d. Serial Number (if applicable)

4. Identification of Printer for Hard Copy Interpretation (mandatory even for facilities performing only soft copy interpretation)

a. Printer Manufacturer
b. Printer Model
c. Year of Manufacture
d. Serial Number

5. Final Interpretation Review Monitor Identification (if soft copy display is available)

a. Monitor Manufacturer
b. Monitor Model
c. Year of Manufacture
d. Serial Number

6. Phantom Identification

a. Phantom Manufacturer
b. Phantom Model

7. Personnel Qualifications

a. Interpreting Physicians who are qualified to interpret full field digital mammograms (see Qualified Personnel)
b. Radiological Technologists who are qualified to perform full field digital mammography examinations and the manufacturer recommended quality assurance tests (see Qualified Personnel)
c. Medical Physicists who are qualified to perform equipment evaluations and/or surveys of full field digital mammography units (Qualified Personnel)

8. Report of Mammography Equipment Evaluation (MEE) (must have been conducted in accordance with 900.12(e)(10) within the 6 months prior to request for use approval)

a. Statement that equipment performance, as required under the following sections of the MQSA final regulation 21 CFR 900.12(b), is met:
(1) Prohibited Equipment
(2) Specifically Designed for Mammography
(3) Motion of Tube-Image Receptor Assembly
(4)(iii) Removable Grid (if applicable to the FFDM system used)
(5) Beam Limitation and Light Fields
(6) Magnification
(7) Focal Spot Selection
(8) Compression
(9) Technique Factor Selection and Display (GE systems may use AOP instead of AEC in this requirement)
(10) Automatic Exposure Control (GE system may use AOP instead of AEC in this requirement)
(14) Lighting (if hard copy display is used for image evaluation)
(15) Film Masking Devices (if hard copy display is used for image evaluation)

b. The results of quality control tests as required under the following sections of the MQSA final regulations 21CFR 900.12(e):
(4)(iii) Compression Device Performance
(5)(i) Automatic Exposure Control Performance (if applicable to the FFDM-DR system used)
(5)(ii) Kilovoltage Peak Accuracy and Reproducibility
(5)(iii) Focal Spot Condition (Resolution)
(5)(iv) Beam Quality and Half-Value Layer
(5)(v) Breast Entrance Air Kerma and AEC Reproducibility (if applicable to the FFDM-DR system used)
(5)(vi) Dosimetry
(5)(vii) X-Ray Field/Light field/Image receptor/Compression paddle alignment
(5)(ix) System Artifacts

(5)(x) Radiation Output
(5)(xi) Decompression (or alternative standards allowed for these requirements)
(6) Quality Control Tests – Other Modalities (Facilities must perform all applicable FFDM-DR manufacturer recommended quality control tests including the medical physicist's tests for the Soft Copy Display system)
c. The results of the phantom image quality tests, including a sample image
d. If any of the requirements in 8 a, b, or c are not met, submit documentation of successful corrective action
e. If any of the requirements in 8 a or b are not performed, explain why the requirement is not applicable
f. Date of the MEE
g. Name and address of the physicist(s) who performed the MEE

9. FFDM-DR Manufacturer's Quality Control Program

a. Name of the Quality Control Manual
b. Year published
c. Revision number, if not the original
d. Printing number, if not the original

10. Signature

Qualified Personnel

Interpreting Physicians

PERSONNEL QUALIFICATIONS: INTERPRETING PHYSICIANS WHO ARE QUALIFIED TO INTERPRET DIGITAL MAMMOGRAMS
List the current interpreting physicians who:

(1) meet all the requirements of CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *; AND
(2) began interpreting full field digital mammograms prior to April 28, 1999.

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List the current interpreting physicians who:

(1) meet all the requirements of 21 CFR 900.12(a)(1) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;

(2) began interpreting full field digital mammograms after April 28, 1999; AND
(3) have 8 hours of initial training in Full Field Digital Mammography*.

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* Supporting documentation for these requirements will be checked during annual MQSA inspections.

Radiologic Technologists

PERSONNEL QUALIFICATIONS: RADIOLOGIC TECHNOLOGISTS WHO ARE QUALIFIED TO PERFORM DIGITAL MAMMOGRAMS
List the current radiologic technologists who:

(1) meet all the requirements of 21 CFR 900.12(a)(2) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *; AND
(2) began performing full field digital mammography examinations prior to April 28, 1999.

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List the current radiologic technologists who:

(1) meet all the requirements of 21 CFR 900.12(a)(2) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;
(2) began performing full field digital mammography examinations after April 28, 1999; AND
(3) have 8 hours of initial training in Full Field Digital Mammography*.

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*Supporting documentation for these requirements will be checked during annual MQSA inspections.

Medical Physicists

PERSONNEL QUALIFICATIONS: MEDICAL PHYSICISTS WHO ARE QUALIFIED TO PERFORM FFDM SURVEYS
List the current medical physicists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *; AND
(2) began performing equipment evaluations and/or surveys of full field digital mammography units prior to April 28, 1999

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List the current medical physicists who:

(1) meet all the requirements of 21 CFR 900.12(a)(3) "Mammography Quality Standards; Final Rule" that became effective on April 28, 1999 *;
(2) began performing equipment evaluations and/or surveys of full field digital mammography units after April 28, 1999; AND
(3) have 8 hours of initial training in Full Field Digital Mammography*.

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* Supporting documentation for these requirements will be checked during annual MQSA inspections.

Lead Interpreting Physician Attestation to Staff Personnel Qualifications

To the best of my knowledge and my belief, the information provided in this document is true and correct. I understand that FDA may request additional information to substantiate the statements made in the document. I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under MQSA, or both.

Signature (Lead Interpreting Physician) _____
Print Name_____
Date_____